## **REMARKS/ARGUMENTS**

Reconsideration of this application is respectfully requested in view of the foregoing amendments and the following remarks.

Response to Rejection of Claim 22 under 35 U.S.C. § 101 and 112, First Paragraph

The examiner has rejected claim 22 under 35 U.S.C. § 101 on the grounds that the invention of claim 22 is not supported by either a supported specific asserted utility or a credible or well established utility. In particular, the examiner urges that the specification does not provide sufficient evidence or experimentation which shows that the compound of claim 22 can cure a patient with AIDS. The examiner also urges that in view of the lack of utility, the invention is not enabled because one skilled in the art would not know how to use the claimed invention. Applicant has carefully considered these rejections but they are most respectfully traversed for the reasons discussed below.

Applicant submits that contrary to the examiner's observation, applicant has indeed asserted a specific and substantial utility which pertains to the anticancer and anti-AIDS virus utility which is expressly stated in applicant's specification. It appears that the examiner may consider applicant's asserted utility as not being credible. However, the examiner has not met his burden which requires establishing a *prima facie* showing of no specific and substantial credible utility. In this regard the examiner's attention is directed to MPEP § 2107 which states that where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish

that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. In this regard MPEP § 2107 states in part:

The *prima facie* showing must contain the following elements:

- (i) an explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;
- (ii) support for factual findings relied upon in reaching this conclusion; and
- (iii) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

Furthermore, MPEP § 2107 also states in part:

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

In view of the above, it is clear that applicant's asserted utility must be considered as a true statement of fact unless the examiner can first establish by sound scientific reasoning supported by an appropriate factual finding and an evaluation of all relevant evidence of record that the asserted utility is not credible. The burden only shifts to applicant to establish the credibility of the asserted utility after the examiner has met his burden as described above. The examiner has failed to meet this burden and thus applicant cannot be required to establish the credibility of the asserted utility.

Nothwithstanding the above, applicant has amended claim 22 to recite that the composition is used for inhibiting the AIDS virus, not "curing" the AIDS virus as initially claimed. This utility is specific, substantial and credible in view of the experimental results listed in table 2 on page 19 of the specification. The data contained in table 2 illustrates that the pharmaceutical composition of applicant's invention has a clear inhibitory effect on the AIDS virus.

In view of the above, applicant submits that claim 22 is in full compliance with 35 U.S.C. § 101 and § 112.

## II Response to Rejections Under 35 U.S.C. § 102(b)

Claims 1-4,7,9,13,19-22,23 and 24 have been rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/00265 published 10 January 1991. Applicant has carefully considered this rejection but it is most respectfully traversed for the reasons discussed below.

Regarding claims 1-4,7,9,13,19-22,23 and 24, applicant submits that the subject matter of these claims and the cited reference WO 91/00265 are different because (1) the structure of applicant's compound is different from that of the prior art, and (2) the substituted functional groups of the anthraquinone derivatives are required to be located symmetrically at the 2,6-positions in the prior art, but no similar requirements can be found for the functional groups on the anthraquinone derivatives of the present patent application, and (3) the functional groups on the anthraquinone derivatives of the present patent application are different from those of the cited reference.

The formula (I) shown on page 3 of the specification and claim1 in the present patent application has following structure:

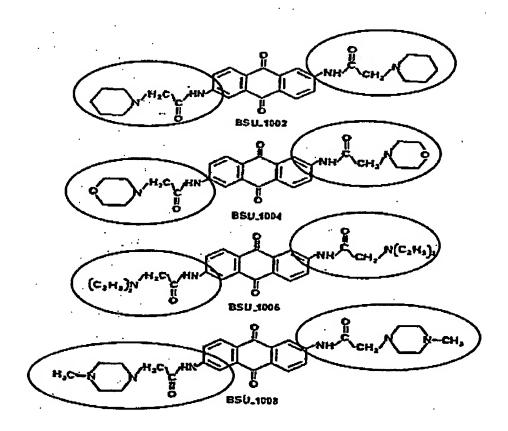
Applicant's compound is an anthraquinone ring substituted with a guanidoacetamide group or a benzyl carbamidoacetamide group.

However, the structure disclosed in the cited reference WO 91/00265 fails to disclose an anthraquinone ring substituted with functional groups illustrated above (see the structures listed following):

According to the description of the cited reference WO 91/00265, functional groups of NR<sup>1</sup>R<sup>2</sup> can be: -piperidine, -morpholine, -diethylamine, -4-methyl-piperazine, -2-(2-hydroxyethyl)piperidine, -4-(2-hydroxyethyl)piperidine, -2-hydroxymethyl-piperidine or -N,N-diethanolamine (table 1, page 5 of WO 91/00265).

Comparing these two structures illustrated above--i.e. the structures described in the present application and those of the cited reference, circles marked on the structure of cited reference indicate the difference between itself and the present patent application. Obviously, the structure of the compound of formula (I) of present patent application is very different from the compound described in the cited reference WO 91/00265.

(2) The anthraquinone derivatives of the cited reference WO 91/00265 require that the substituted functional groups has to be symmetrically positioned at the 2,6-positions on the anthraquinone ring. In this regard the examiner's attention is directed to claims 1-2, pages 1, 2 and 5-8 and examples 1-18 of WO 91/00265. Further, more evidence can be found through the fact that 13 anthraquinone compounds listed on page 6-8 of the specification of the prior art WO 91/00265 as following structures:



Those substituted functional groups of the structures listed above all symmetrically positioned at 2,6-sites on the anthraquinone ring as indicated with circles above.

On the contrary, regarding to the structures of compounds of the present patent applications, symmetrically positioned of the functional groups is not a requirement for inhibiting tumor cells as described on the specification.

(3) Not only the positions of the functional groups of the present patent application are different from those of the cited reference, but also the suitable functional groups of the present patent application are not identical to those of the cited reference. Base on the opinion (2) described above and page 2 of the specification, suitable functional groups of the present patent application are guanidoacetamide or benzyl carbamidoacetamide groups, but refer to claim 1-3, page1-2, 5-8 and examples 1-18 in the specification of the prior art WO 91/00265, no guanidoacetamide or benzyl carbamidoacetamide groups is disclosed. Even the 13 anthraquinone compounds listed in table 1 of the prior art WO 91/00265, the functional groups of NR<sup>1</sup>R<sup>2</sup> is possible to be -piperidine, -morpholine, -diethylamine, -4methyl-plperazine, -2-(2-hydroxyethyl)piperidine, hydroxyethyl)piperidine, -2-hydroxymethyl-piperidine or -N,Ndiethanolamine. The major substituted functional group of the present patent application is guanidinyl group, however, the functional groups include no guanidinyl group of the prior art WO 91/00265.

In addition to the above-discussed distinctions, applicant submits that claims 2, 3, 7, 9 and 13 are further distinguished over the cited reference for the following reasons.

Claim 2 requires that  $R_1$ ,  $R_2$  and  $R_3$  are either hydrogen or amino.  $R_3$  of applicant's claimed compound corresponds to either  $R_1$  or  $R_2$  of the prior art compound. However, neither one of  $R_1$  or  $R_2$  of the prior art compound may be hydrogen or amino as required by claim 2.

Claim 3 is similarly distinguished over the prior art reference since claim 3 also requires that R<sub>3</sub> is hydrogen or amino. In addition, claim 3 also limits R<sub>4</sub> to a group which is not permitted by R<sub>1</sub> or R<sub>2</sub> of the prior art compound.

Likewise, claim 7 limits  $R_4$  to a group which is not permitted by  $R_1$  or  $R_2$  of the prior art compound.

The particular compounds of claims 9 and 13 are not disclosed by the cited reference.

In view of the foregoing remarks, reconsideration and allowance of the application are now believed to be in order, and such action is hereby solicited. If any points remain in Issue that the examiner feels may be best resolved through a personal or telephone interview, the examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Date: October 20, 2003

**BACON & THOMAS** 625 Slaters Lane, Fourth Floor Alexandria, Virginia 22314 Phone: (703) 683-0500 s:\producer\}db\wood & MU\LEE 022,411\Amend 01.wpd Respectfully submitted.

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